CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Notice of Intent to Re-Certify
Hazardous Waste Environmental Technology

The California Environmental Protection Agency, Department of Toxic Substances Control (DTSC) intends to re-certify the following hazardous waste environmental technology:

The SCIGEN NEUTRALEX technology for treating formaldehyde in waste neutral buffered Formalin from histopathology specimen preservation and use of automated histopathology tissue processors.

Applicant: SCIGEN, Inc.
333 East Gardena Blvd
Gardena, California 90249

Section 25200.1.5., Health and Safety Code, enacted by Assembly Bill 2060, authorizes DTSC to certify the performance of hazardous waste environmental technologies. Only technologies which are determined to not pose a significant potential hazard to the public health and safety or to the environment when used under specified operating conditions may be certified. Incineration technologies are explicitly excluded from the certification program.

The purpose of the certification program is to provide an independent technical evaluation of technologies to identify those meeting applicable quality standards, so as to facilitate regulatory and end-user acceptance and to promote and foster growth of California's environmental technology industry.

DTSC makes no express or implied warranties as to the performance of the manufacturer's product or equipment. The end-user is solely responsible for complying with the applicable federal, state, and local regulatory requirements. Certification does not limit DTSC's authority to require additional measures for protection of public health and the environment.

By accepting certification, the manufacturer assumes, for the duration of certification, responsibility for maintaining the quality of the manufactured equipment and materials and their operation at a level equal to or better than was provided to obtain certification and agrees to be subject to quality monitoring by DTSC as required by the statute under which certification is granted.

DTSC's proposed decision to re-certify is subject to public review and comment. Written comments must be submitted to DTSC no later than 30 days after publication of this notice. All comments will be considered and appropriate changes will be made prior to publishing DTSC's final decision.

Additional information supporting DTSC's proposed decision is available for review. Requests for additional information or comments concerning this proposed decision should be submitted to the following address:

California Environmental Protection Agency
Department of Toxic Substances Control
Office of Pollution Prevention and Technology Development
P.O. Box 806
301 Capitol Mall, 1st Floor
Sacramento, California 95812-0806
Attn: Dr. Bruce La Belle (916) 324-2958

Background

The Scigen Neutralex technology was originally certified for a three-year term, effective June 29, 1997. The final decision to certify was published in the May 30, 1997, California Regulatory Notice Register, Volume 97, Number 22-Z. Scigen has not changed their technology since the original certification was issued. The final decision published on May 30, 1997, includes a description of the technology, the certification statement and associated conditions and limitations, and the technical basis for the original certification decision. A copy of this information may be obtained from DTSC.

Effect on Current Certification Status

Pursuant to Title 22, California Code of Regulations section 68100, the existing certification shall remain valid during the public comment period for this proposed recertification decision, during the period in which DTSC responds to any comments received and prepares a final decision, and during the pubic notice period for the final re-certification decision.

Basis for Re-Certification

Scigen stated in their application for re-certification that the Neutralex technology has not changed since it was originally certified. DTSC staff contacted three users of the Neutralex technology to gather information on its performance during the period of certification. A pathology laboratory contacted uses Neutralex to treat approximately 1 gallon of formalin waste per day, primarily from automated tissue processors (ATP waste). A Kaiser Permanente regional pathology laboratory treats approximately 4 gallons of per day of wastes from ATP and decantate from tissue specimens. Stanford University treats approximately 100 - 140 gallons per month from tissue processors, gross pathology specimen preservation, and decanting of pre-filled pathology specimen containers. Each of the users stated that the Neutralex technology worked well. None had experienced problems with the technology. All tested the treated wastes with the Scigen formaldehyde test kit and pH paper prior to disposal, and found treated wastes to have low residual formaldehyde. One of the users had been inspected by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and two by the College of American Pathologists (CAP). One of the users had been inspected by their CUPA. None of the inspectors had identified problems with the treatment operations.

Regulatory Considerations

Title 22, California Code of Regulations, Section 67450.20, specifies that treatment of formaldehyde by health care facilities using any technology certified as effective for that purpose is authorized for operation under a grant of conditional exemption. The treatment must be operated pursuant to the conditions imposed on the certification. In addition, the generator conducting the treatment must comply with the conditions of the Conditional Exemption in Section 25201.5 of the Health and Safety Code. The reader should refer to these statutory and regulatory sections for additional information.

Certification Reference

As a holder of a valid hazardous waste environmental technology certification, Scigen is authorized to use the certification seal (California Registered Service Mark Number 046720) during the

term of the certification. Scigen shall cite the certification number and date of issuance in conjunction with the certification seal whenever it is used.

When providing information on the certification to an interested party, Scigen shall at a minimum provide the full text of the original and re-certification decisions as published in the May 30, 1997, and June 23, 2000, California Regulatory Notice Registers.

Duration of the Certification

This re-certification will remain in effect for the period of three years from the date of issuance, unless it is revoked for cause or amended.